

Attorney Docket No.: 5784.210-US
USSN: 09/671,461
Filed: 09/27/2000
Inventor: Arne Staby
Express Mail Label No.: EV 246879127 US

REMARKS

Claims 2, 4, 6 and 11-29 are pending in the present application. Support for new claims 26-29 is found throughout the application including Examples 13-17.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

The Examiner provisionally rejected claims 2, 4, 6 and 11-25 under the judicially created doctrine of obviousness-type double patenting over claims 3, 4, 8, 9, and 12-38 of co-pending application 10/176,410 on the basis that the rejected claims of the pending application and the cited claims of the co-pending application 10/176,410 are "obvious variations of a method for purifying a peptide or a specific method from a mixture comprising the peptide and related impurities by eluting the impurities from the anion exchange chromatography with a solution comprising an organic modifier, water, optionally a salt component and optionally a buffer" (page 4 of Office Action).

Applicant respectfully traverses this rejection.

While the claims of the present application and of co-pending application 10/176,410 ("the '410 application") are both directed to purification of peptides on an anion exchange chromatography matrix, the '410 claims separate the peptide from impurities in a **single** step in the presence of an organic modifier whereas the pending claims are directed to a **two** step process whereby the first step comprises eluting impurities in the presence of an organic modifier **and the second step comprises eluting the peptide in the absence of an organic modifier**. It is Applicant's position that there is nothing in the claims of the co-pending '410 application that teaches or suggests the two step process set forth in the claims of the present application. Moreover, the Examiner has provided no evidence of any such teaching or suggestion other than the conclusory statement that the claims of the present application are "obvious variations" of the claims of the '410 application.

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Applicant therefore respectfully requests withdrawal of this obviousness-type double patenting rejection.

Rejections Of The Claims Under 35 U.S.C. 112, Second Paragraph

The Examiner rejected claims 2, 4, 6 and 11-25 as indefinite because of the terms “optionally a salt component” or “optionally a buffer”. In particular, the Examiner states that “it is not clear how a solution comprising an organic modifier, water, but without a a salt component and without a buffer, can have linear or step gradient or isocratically in salt component during the elution, and how a pH of the solution is maintained without a buffer” (page 5 of Office Action).

Applicant respectfully traverses this rejection.

First, the terms (“optionally a salt component” or “optionally a buffer”) recited in step (a) of the rejected claims have a clear and definite meaning as required by the second paragraph of section 112. Specifically, the phrase “a solution comprising an organic modifier, water, optionally a salt component and optionally a buffer” would be clearly understood to mean that the solution used in step (a) of the claimed methods can contain:

- 1) organic modifier and water;
- 2) organic modifier, water and buffer;
- 3) organic modifier, water and salt; or
- 4) organic modifier, water, buffer and salt.

Further, the recitation in step (a) that the above solution can be used “at a linear or step gradient or isocratically in salt component” would have a clear and definite meaning as the terms “gradient elutions” and “isocratic elutions” are known to those skilled in the art. In particular, the phrase “at a linear or step gradient or isocratically in salt component” would be understood to mean that if salt is present in the solution described above, then use of the salt-containing solution in a linear or step gradient would be carried out by using a linear or step gradient of the salt component of the solution (as indeed was done in Examples 13-17) whereas use of the salt-containing solution to conduct an isocratic elution would be carried out by holding the

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concentration of the salt component of solution constant throughout the elution. Accordingly, Applicant submits that the terms "optionally a salt component" or "optionally a buffer" have a clear and definite meaning to one of ordinary skill in the art and hence, are in compliance with the requirements of section 112, second paragraph.

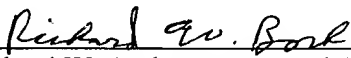
Second, to the extent that the Examiner is unclear how an elution of impurities can be achieved in the absence of both salt and buffer¹, Applicants submits that elution of such impurities from an anion exchange chromatography column can readily be achieved under such conditions. For example, if solution A to be used for anion exchange chromatography is a solution containing water and organic modifier, one could prepare a solution B from solution A by adjusting the pH of some of solution A with an acid and then make a gradient from solution A to solution B thereby eluting the impurities via a pH gradient.

Accordingly, in view of the above remarks, Applicant respectfully requests withdrawal of this rejection.

In sum, it is respectfully submitted that the present application is in condition for allowance and early and favorable consideration to that end is respectfully requested

Respectfully submitted,

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¹ The Examiner's citation in the definiteness rejection to the disclosure in Examples 13-17 of elution of impurities using a salt gradient is not understood. For the reasons set forth in the present Amendment, the terms "optionally a salt component" or "optionally a buffer" have a clear and definite meaning to one of ordinary skill in the art, the elution of related impurities using a solution containing an organic modifier, water, optionally a salt component and optionally a buffer is clearly described in the application as filed and one of ordinary skill in the art would clearly know how to achieve elution of impurities in the absence of both salt and buffer.